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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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MINTZ, LEVIN, COHN, FERRIS, GLOVSKY
AND POPEO, P.C.
ONE FINANCIAL CENTER
BOSTON, MA 02111

EXAMINER
MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 09/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/973,449	BADER ET AL.	
	Examiner	Art Unit	
	Marjorie A. Moran	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☒ Claim(s) *11 and 22* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 October 2001* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Information Disclosure Statement

The information disclosure statements (IDS's) filed on 2/11/02 and 1/27/03 have been considered in full.

It is noted that the specification provides a list of references on pages 15-16. Applicant is reminded that a listing of references in the specification is not a proper information disclosure statement as set forth under 37 CFR 1.98(b). Therefore, unless the references have been cited by the examiner on form PTO-892 or on one of the IDS's filed 2/11/02 or 1/27/03, they have not been considered.

Claim Objections

Claims 11 and 22 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 11 and 22 appear to recite an intended use for the methods of claims 1 and 13, respectively. Neither recites an active, positive method step nor any limitation of a previously recited step nor a limitation of any other element of a parent claim. Applicant is reminded that an intended use is generally not accorded any patentable weight where it merely recites the purpose of a process. See In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). The

intended use recited in claims 11 and 22 does not materially limit the process steps of claims 1 and 13, respectively, and is therefore not considered a limitation of the methods of the parent claims. For these reasons, claims 11 and 22 fail to further limit the methods of their respective parent claims and are objected to.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites use of an "Eq. 2" and claim 13 recites use of an Eq. 1",each ins a step (b). None of the claim recites an actual equation. The specification sets forth equation labeled "Eq. 1", "Eq. 1" and "Eq. 3" on page 8. It is noted that the specification teaches a plethora of equations in addition to those of page 8. It is unclear what equations or equations applicant intends, if any, to be represented by the "Eq. 1" and Eq. 2" recited in the instant claims, therefore the claims are indefinite.

Applicant's attention is directed to MPEP 2173.05(s), which states, "Where possible, claims are to be complete in themselves. .... Incorporation by reference is a necessity doctrine, not for applicant's convenience." Ex parte Fressola, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) (citations omitted)."

If applicant intends "Eq. 1" and "Eq. 2" to represent the specific equations disclosed on page 8 of the specification, then the claims are further indefinite as it is unclear what the terms of the equations are intended to represent. For example, page 7 of the specification teaches that for a normal standard deviate z (standard deviate of what?), $\propto$ is defined in terms of deviate $z_{\propto}$. However, page 7 also defines $z_{\propto}$ as being equal to a constant (5.33) for a genome scan. Does applicant intend $z_{\propto}$ to be a constant or a variable in Eq. 1 of page 8? If a constant, what is it? If a variable, how is it to be determined for the specific method recited in the claims?

For the reasons set forth above, claims 1 and 13 are indefinite. As claims 2-12 and 14-23 fail to remedy the indefiniteness of parent claims 1 and 13,claims 2-12 and 14-23 are also indefinite. For purposes of search, the examiner interpreted "Eq.1" and "eq.2" to represent the similarly labeled equations of page of the specification.

Claims 1, 5, and 6 recite the term "predetermined" as applied to an "upper limit" and a "lower limit" of phenotypic values. No step of "determining" a limit, either upper or lower, is recited in the claims, therefore it is unclear what is meant by a "predetermined" limit. The specification does not set forth limits for phenotypic values nor exemplify any particular "upper" or "lower" limits which may be taken as definitions of a "predetermined" upper or lower limit. As one skilled in the art would not know the metes and bounds intended by applicant for a "predetermined" upper or lower limit of phenotypic values, the claims are indefinite.

Claims 1 and 13 recite the term "predetermined value" with regard to an allele frequency difference. There is no step of "determining" a value of an allele frequency

difference in the claims, therefore it is unclear what is meant by a "predetermined value". The specification does not set forth or exemplify any "values" which may be taken to be a definition of a "predetermined value". As one skilled in the art would not know the metes and bounds intended by applicant for a "predetermined value", the claims are indefinite.

Claim 5 limits the setting of a lower limit and an upper limit such that a pool (of DNA) "ranges" to include various percentages of a population. Once a limit is set, then the membership of the pool which results is generally also considered "set"; i.e. static. It is therefore unclear whether applicant intends the lower (and/or upper) limit to be variable such that the resulting pool membership falls within the stated range, or intends the pool membership itself to be variable despite having a set limit. As it is unclear what limitations applicant intends, the claim is indefinite.

Claims 8 and 19 recite the term "may be" with regard to individuals. The term "may be" renders the claims indefinite as it is unclear whether the phrase(s) following the term are intended to be positive limitations. This rejection may be overcome by replacing "may be" with --are-- in each claims, if this is consistent with applicant's intent.

Claims 11 and 22 recite a limitation of method claims "for determining the genetic basis of disease predisposition". It is unclear what limitation of each parent method is intended. No active method steps are recited in either claim, nor does either claim recite any limitation of a previously recited method step. See above. As it is unclear what, if any, limitation of a parent claim is intended, claims 11 and 22 are indefinite.

Conclusion

Claims 1-23 are rejected; claims 11 and 22 are objected to.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. MURANTY et al. (Genet. Res. (1997) Vol. 70, pp. 259-265) teaches a method of selective genotyping similar to that claimed wherein formulae are used to determine the optimal number of individuals for use in selecting pools. MURANTY teaches that his formulae are obtained in the first two steps in a computer program (p. 263), but does not specifically teach what formulae or equations were used, therefore the examiner can not determine whether the formulae of MURANTY are the same as those interpreted to be recited in the instant claims (see above). Applicant invited to comment on any differences, if known, between the equations of the instant specification and those of MURANTY.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3524.

MARJORIE MORAN
PATENT EXAMINER

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